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AUG 6 2001

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Patent Department, Q-148
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth TX 76134

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,378,703

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,378,703, which claims the human drug AZOPT™ (brinzolamide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 723 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 723 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 27, 2000 (65 Fed. Reg. 4435). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,620 - 863) + 429
= 808 days

Since the regulatory review period began August 23, 1992, before the patent issued (January 3, 1995), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 23, 1992 to January 3, 1995 is ~~808~~ 863 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (April 1, 1998) plus any patent term extension cannot exceed fourteen years. The period of extension calculated above 808 days, would extend the patent from the original expiration date of April 9, 2010 (pursuant to the terminal disclaimer dated June 20, 1994 (the expiration date of U.S. Patent No. 5,153,192) to June 25, 2012, which is beyond the 14 year limit (14 years after the approval date is April 1, 2012) set forth in 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its expiration date, April 9, 2010, to and including April 1, 2012, or 723 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,378,703
Granted	:	January 3, 1995
Original Expiration Date	:	April 9, 2010
Applicant	:	Thomas R. Dean, et al.
Owner of Record	:	Alcon Laboratories, Inc.
Title	:	Sulfonamides Useful as Carbonic Anhydrase Inhibitors
Classification	:	514/222.8
Product Trade Name	:	AZOPT™ (brinzolamide)
Term Extended	:	723 days
Expiration Date of Extension	:	April 1, 2012

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Karin Tyson

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
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Rockville, MD 20852

RE: AZOPT™ (brinzolamide)
FDA Docket No.: 98E-0837